National Confectioners Association
ALWAYS A TREAT

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February 19, 2019

Via electronic submission

Office of Environmental Health Hazard Assessment
1515 Clay Street, 16th Floor
Oakland, CA 94612
Attention: Anna Smith, Food Dye Study

RE: Comments in Response to OEHHA Request for Information on the Neurologic and Neurobehavioral Impacts of Synthetic Food Dyes (October 22, 2018)

Dear Ms. Smith:

The **National Confectioners Association** (NCA) is the trade organization that advances, protects and promotes chocolate, candy, gum and mints, and the companies that make these special treats. As the leading association for the U.S. confectionery industry, we help ensure the public understands and appreciates the unique role that chocolate, candy, gum, and mints can play in a happy, balanced lifestyle. Confections are produced in all 50 states, creating jobs for approximately 54,000 workers in nearly 1,300 manufacturing facilities across the country. For every job created in confectionery manufacturing, another ten are supported in related industries. In total, more than 607,000 American jobs are supported by the U.S. confectionery industry. America's leading chocolate and candy companies recently launched the Always A Treat Initiative, [1] a commitment to transparency, portion guidance, and consumer education.

We would like to thank the California Office of Environment Health Hazard Assessment (OEHHA) for its mission to protect and enhance the health of Californians and the state's environment through scientific evaluations that inform, support and guide regulatory and other

[1] AlwaysATreat.com

actions. We further appreciate the opportunity to provide comments on this new area of study for OEHHA. NCA's viewpoint is threefold:

1. The Food and Drug Administration is the Appropriate Regulatory Body to Oversee the Regulation of Color Additives

Congress entrusted the Food and Drug Administration (FDA) to serve as the nation's expert on food safety and labeling. As such, FDA is the entity responsible for making sure all foods are safe for consumption, contain only approved ingredients, and are properly labeled. This includes color additives. The legal framework for FDA's oversight of color additives is found both in the statute and in the agency's implementing regulations.

Specifically, the Federal Food, Drug, and Cosmetic Act (FFDCA) provides that a substance that imparts color is a color additive and is subject to premarket approval requirements unless the substance is used solely for a purpose other than coloring.[1] A color additive, as defined by regulation, is any dye, pigment, or other substance that is capable of imparting color to a food, drug, or cosmetic or to the human body.[2] Therefore, all substances used to impart color must be pre-approved by FDA and comply with the color additive regulations; otherwise they are adulterated and/or misbranded under the FFDCA.[3] Adulterated and misbranded products cannot be introduced into commerce, sold, or distributed.

When reviewing a proposed color additive, FDA determines whether there is "a reasonable certainty of no harm" to consumers when the color additive is used properly at its intended level and for its intended purpose.[4] In evaluating the safety of a color additive, FDA considers factors including probable consumption, cumulative effect in the diet, and evaluation by experts qualified by scientific training and experience. Each color additive is permitted only for the intended use stated in its listing regulation including the types of foods it can be used in, the maximum amount allowed to be used, and any labeling requirements. Accordingly, FDA's sole jurisdiction over the review, approval, and enforcement of color additive use and safety is clear and continuous.

2. The FDA has Already Reviewed the Issue of Potential Neurobehavioral Impacts of Color Additives in Children

As a science-based agency, one of FDA's roles is to assure that color additives are safely and appropriately used. FDA continually monitors a color additive's safe use, including consideration of new safety and data information. Further, all color additives are subject to ongoing safety review as science and methods of testing continue to improve.

FDA has reviewed and will continue to examine the effects of color additives on children's behavior. In 2011, the FDA Food Advisory Committee (Committee) was charged with review of

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[1] 21 USC § 321(t)(1).
[2] 21 CFR § 70.3(f).
[3] *See* 21 USC § 342(c); *see also* § 343(m).
[4] 21 CFR § 70.3(i).

all available relevant data on the possible association between consumption of certified color additives in food and hyperactivity in children, and to advise FDA as to what action, if any, was warranted to ensure consumer safety.[1]

The agency conducted a thorough review of the published literature on color additives and behavioral effects on children. Based on the review of the data, FDA concluded that the totality of scientific evidence indicates that a causal relationship between exposure to color additives and hyperactivity in children in the general population has not been established, but some evidence suggests that certain children may be sensitive to color additives.[2] After the Committee's review, FDA stated that it will continue to evaluate emerging science to ensure the safety of color additives approved for use.[3] At this time, FDA advises consumers that "results on studies about a link between color additives and ADHD have been inconclusive, inconsistent, or difficult to interpret due to inadequacies in study design."[4]

3. **The Office of Environmental Health Hazard Assessment (OEHHA) should carefully consider its Conclusions to Avoid Unintended Impacts on Vulnerable Populations**

In its review of information on the neurologic and neurobehavioral impacts of synthetic food dyes, we encourage OEHHA to carefully consider its conclusions in terms of impacts to consumers, their children, and availability of options to food sources. Regulatory agencies making broad recommendations can have unintended consequences that may impede serving the public interest. For example, over the last decade, there have been varying degrees of concern regarding Bisphenol A (BPA) in canned foods. However, the science is inconclusive, and limiting the availability of (or creating a situation where consumers do not want to purchase) canned fruits and vegetables would create a nutritional disparity for low income households or those without refrigerators for produce in fresh fruit and vegetable food deserts.

It also is important to keep in mind that consumer understanding of complex scientific issues may vary depending on the audience. Therefore, we support transparent and open dialogue between OEHHA and the food industry to ensure that review of the issues and relevant conclusions are scientifically valid, and clearly communicated to all interested parties.

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[1] Food Advisory Committee Meeting, Certified Color Additives and Childhood Hyperactivity Charge and Questions (Mar. 30-31, 2011), https://wayback.archive-it.org/org-1137/20170406211644/https://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/FoodAdvisoryCommittee/UCM247999.pdf.

[2] Background Document for the Food Advisory Committee: Certified Color Additives in Food and Possible Association with Attention Deficit Hyperactivity Disorder in Children (Mar. 30-31, 2011), https://wayback.archive-it.org/org-1137/20170406211659/https://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/FoodAdvisoryCommittee/UCM248549.pdf.

[3] Color Additives Questions and Answers for Consumers (page last updated Jan. 4, 2018) https://www.fda.gov/food/ingredientspackaginglabeling/foodadditivesingredients/ucm488219.htm.

[4] Linda Katz, Food and Drug Administration, How Safe Are Color Additives?, https://www.foodsafety.gov/blog/color_additives.html (last reviewed Jan. 24, 2019).

NCA further supports comments (expected to be submitted to OEHHA) from the International Association of Color Manufacturers who have conducted a thorough literature review and assessment of the relationship between color additives and neurological disorders. We urge OEHHA to consider all relevant issues of scientific methodology when reviewing existing literature including the population, number of participants or observations, proper controls, sensitivity of measurement, statistical analysis and interpretation of results.

In summary, NCA is supportive of US food safety protocols and rigorous scientific review of food ingredients, we, however, do not believe that OEHHA is the appropriate agency for such a review on this topic as it is outside its mandate. NCA supports the US FDA as the appropriate regulatory body to oversee the regulation of color additives.

Thank you for your consideration.

Sincerely,

Debra L. Miller, PhD
Senior Vice President
The National Confectioners Association